

LARSEN ET AL. -- 09/890,567
Client/Matter: 068800-0282776

IN THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. – 33. (Cancelled).
34. (New) A method for cancer diagnosis or prognosis which comprises:
- (a) treating a sample from a human or animal subject with a solid phase under conditions to bind telomerase to the solid phase;
 - (b) separating the solid phase from the treated sample to form a test sample which is optionally treated to elute bound telomerase from the solid phase; and
 - (c) assaying the test sample for telomerase activity, wherein detection of telomerase activity in the sample is indicative of cancer in the subject.
35. (New) A method according to claim 34, wherein the sample comprises target whole cells, which are treated in step (a) to form a lysate to release telomerase for binding to the solid phase.
36. (New) A method according to claim 34, wherein the solid phase comprises a particulate material.
37. (New) A method according to claim 36, wherein the particulate material comprises polymeric beads.
38. (New) A method according to claim 37, wherein the polymeric beads have a diameter in the range of from 1 μ to 6 μ m.
39. (New) A method according to claim 36, wherein the particulate material is magnetic.
40. (New) A method according to claim 34, wherein the step (c) of assaying for telomerase activity uses a telomeric repeat assay protocol.

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41. (New) A method for cancer diagnosis or prognosis which comprises:
- (a) treating a sample from a human or animal subject with a solid phase under conditions to bind telomerase to the solid phase;
 - (b) separating the solid phase from the treated sample; and
 - (c) assaying the solid phase for telomerase activity, wherein detection of telomerase activity in the sample is indicative of cancer in the subject.
42. (New) A method for cancer diagnosis or prognosis which comprises:
- (a) sorting a sample comprising a mixture of cell populations from a human or animal subject to isolate target whole cells in the sample;
 - (b) treating the isolated target whole cells to form a lysate to release telomerase for binding to a solid phase;
 - (c) treating the lysate with the solid phase under conditions to bind telomerase to the solid phase;
 - (d) separating the solid phase from the treated lysate to form a test sample which is optionally treated to elute bound telomerase from the solid phase; and
 - (e) assaying the test sample for telomerase activity, wherein detection of telomerase activity in the sample is indicative of cancer in the subject.
43. (New) A method according to claim 42, wherein the mixture of cell populations is selected from the group consisting of blood, bone marrow, a pleural effusion, urine, saliva, sputum, feces, spinal fluid, a cervical smear, a buccal swab, or a needle biopsy sample.
44. (New) A method according to claim 10, wherein detection of telomerase activity in the sample is further indicative of micrometastasis in the subject.
45. (New) A method for cancer diagnosis or prognosis which comprises:
- (a) sorting a sample to isolate target whole cells in the sample, wherein the sorting comprises flow cytometry sorting or a step of binding the target whole cells to a solid phase affinant for the target whole cells, and the sample comprises a mixture of cell populations from a human or animal subject;
 - (b) treating the isolated target whole cells to form a lysate to release telomerase for binding to a solid phase;

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- (c) treating the lysate with a solid phase under conditions to bind telomerase to the solid phase;
- (d) separating the solid phase from the treated lysate to form a test sample which is optionally treated to elute bound telomerase from the solid phase; and
- (e) assaying the test sample for telomerase activity, wherein detection of telomerase activity in the sample is indicative of cancer in the subject.

46. (New) A method according to claim 45, wherein the affinant comprises an antibody specific to the target cells.

47. (New) A method according to claim 45, wherein the affinant is specific for epithelial cells.

48. (New) A method for cancer diagnosis or prognosis which comprises:

- (a) isolating target whole cells in the sample by binding the target whole cells to a solid phase affinant for the target whole cells, wherein the sample comprises a mixture of cell populations from a human or animal subject;
- (b) treating the isolated target whole cells to form a lysate to release telomerase for binding to a solid phase on which the solid phase affinant is present;
- (c) treating the lysate with the solid phase on which the solid phase affinant is present, under conditions to bind telomerase to the solid phase;
- (d) separating the solid phase from the treated lysate to form a test sample which is optionally treated to elute bound telomerase from the solid phase; and
- (e) assaying the test sample for telomerase activity, wherein detection of telomerase activity in the sample is indicative of cancer in the subject.

49. (New) A method according to claim 48, wherein the affinant comprises an antibody specific to the target cells.

50. (New) A method according to claim 48, wherein the affinant is specific for epithelial cells.

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51. (New) A kit for detecting telomerase activity, comprising a solid phase for binding telomerase and one or more components for assaying for telomerase activity, wherein the solid phase comprises an affinant for binding target whole cells.
52. (New) A kit according to claim 51, wherein the affinant comprises an antibody specific to the target cells.
53. (New) A kit according to claim 51, wherein the affinant is specific for epithelial cells.
54. (New) A kit according to claim 51, wherein the one or more components for assaying telomerase activity comprise a substrate for telomerase elongation.
55. (New) A kit according to claim 54, wherein the substrate for telomerase elongation is present on the solid phase for binding telomerase.
56. (New) A kit according to claim 51, wherein the one or more components for assaying telomerase activity comprise components for a telomeric repeat assay protocol.
57. (New) A kit according to claim 51, wherein the one or more components for assaying telomerase activity include oligonucleotide primers to amplify the telomerase product.
58. (New) A kit for detecting telomerase activity, comprising a solid phase for binding telomerase and one or more components for assaying for telomerase activity, which further comprises a second solid phase for binding target whole cells.
59. (New) A kit according to claim 58, wherein the second solid phase comprises an affinant for binding target whole cells.
60. (New) A kit for detecting telomerase activity, comprising a solid phase for binding telomerase, one or more components for assaying for telomerase activity, and instructions to the user of the kit to use the solid phase to bind telomerase.

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61. (New) A method for detecting telomerase activity, comprising providing a kit comprising a solid phase for binding telomerase and one or more components for detecting telomerase activity, using the solid phase to bind telomerase, and assaying for telomerase activity.

62. (New) A method according to claim 61, wherein the solid phase comprises a particulate material.

63. (New) A method according to claim 62, wherein the particulate material comprises polymeric beads.

64. (New) A method according to claim 63, wherein the polymeric beads have a diameter in the range of from 1 μm to 6 μm .

65. (New) A method according to claim 61, wherein the particulate material is magnetic.